5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

JUL 3 1 2012

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Summary updated: July 18, 2012

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TRADE NAME: VICTUS Femtosecond Laser Platform

COMMON NAME: Ophthalmic Laser

CLASSIFICATION NAME: Laser, Ophthalmic

DEVICE CLASSIFICATION: Class II

PRODUCT CODE HQF (Laser, Ophthalmic)
OOE (Ophthalmic Femtosecond Laser)

Subsequent predicate product codes:
HNO (Keratome, AC powered)
GEX (Powered Laser Surgical Instrument)

SUBSTANTIALLY EQUIVALENT TO:

510(K) NUMBER	PRODUCT TRADE NAME	MANUFACTURER
K033354	FEMTEC Laser Microkeratome	Technolas Perfect Vision GmbH
K110427	FEMTEC Laser System for Capsulotomy	Technolas Perfect Vision GmbH
K113151	iFS Laser System	Abbott Medical Optics
K040204	Zyoptix XP Microkeratome	Technolas Perfect Vision GmbH

Description of the Device Subject to Premarket Notification:

The VICTUS Femtosecond Laser Platform is a precision ophthalmic surgical laser indicated for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea or for patients undergoing anterior capsulotomy during cataract surgery.

The VICTUS Femtosecond Laser Platform is an ophthalmic surgical femtosecond laser designed for cutting a precise corneal flap of pre-selected thickness and diameter. The system works by first being programmed with the depth and diameter at which the flap should be made. The surgeon then fixates the eye with a PMMA contact lens (referred to hereafter as the Patient

Interface) that is connected to the laser via a vacuum tube. Flap thickness of 110 to 200 microns can be achieved in diameters of 6.0 to 9.5 mm.

In addition to the above, the VICTUS Femtosecond Laser Platform allows anterior capsular dissection which is achieved through precise individual micro-photodisruption of tissue, measuring a few microns in diameter, created by tightly focusing ultrashort laser pulses into the targeted capsular tissue. Pre-programmed patterns produce capsular resections of predetermined diameter and height. Capsular cut depth of 2245 to 5000 microns below the corneal surface can be achieved in diameters of 3 to 7 mm.

For both indications for use, laser pulses are delivered through a sterile disposable Patient Interface, consisting of a contact lens and suction clip to provide suction. The contact lens and suction clip assembly creates a reference surface for depth control and fix the eye relative to the delivery of the laser beam. Surgical effects are produced by scanning thousands of individual pulses, producing continuous incisions. The location of the tissue photodisruption is controlled by a fixed laser beam focused through a scanning optic system to the desired location.

The fundamental scientific technology remains the same as previously cleared for the FEMTEC Laser System under K0333354 and K110427. The indication for use for the VICTUS Femtosecond Laser Platform is a combination from those previously cleared under K033354 and K110427.

Indications for Use:

The VICTUS Femtosecond Laser Platform is indicated for use for:

- the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

- for anterior capsulotomy during cataract surgery.

The VICTUS Femtosecond Laser Platform is capable of performing the above indications as previously cleared under the predicate systems discussed within this submission. The first part of the indication is for use in the creation of corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea. This indication for use remains unchanged from that previously cleared under K033354 (for FEMTEC Laser Microkeratome). The second part of the indication is for anterior capsulotomy during cataract surgery. This indication for use remains unchanged from that cleared under K110427 (FEMTEC Laser System for Capsulotomy). The combination of the two indications on one device does not pose any additional concern of safety or effectiveness.

Technical Characteristics Comparison:

The design principle of the VICTUS system is fundamentally the same as the predicate devices. Whereas the predicate devices beam steering and monitoring were provided by separate subassemblies (units), the VICTUS Femtosecond Laser Platform has integrated these subassemblies into one assembly also known as the ARGES Rail assembly. The ARGES Rail assembly is mounted in the application arm of the laser workstation. The main function is to receive the pulsed laser beam from the laser source, control the laser energy, steer the laser beam, and finally to focus the laser beam on to the cornea or lens of the patient's eye. For a treatment, this focus is guided along a well-defined three dimensional path that creates exact cuts in the tissue by laser induced optical breakdown (LIOB). Prior to start of the procedure, the ARGES Rail assembly receives the steering information (instruction list) via a digital interface from the graphical user interface personal computer (GUI-PC). The instruction list contains settings for the pulse energy as well as information on the desired position and speed of delivery. As compared to the predicate Femtec for Anterior Capsulotomy (K110427) which had an external OCT unit included, the VICTUS Femtosecond Laser Platform has an integrated OCT which is

used for OCT guided anterior capsulotomy procedures.

The fundamental algorithms controlling the laser patterns to achieve either flap creation or anterior capsulotomy remain unchanged from those previously cleared in the predicate systems (K033354 and K110427). For flap creation the laser repetition rate has been increased from 12.5 kHz to 160 kHz which effectively shortens flap creation treatment time.

Performance Data:

The VICTUS Femtosecond Laser Platform has undergone testing and is in compliance with applicable safety standards as listed below.

Standard	Title
EN ISO 60601-1	Medical electrical equipment – Part I: General requirements for safety
EN ISO 60601-1-2	Medical electrical equipment – Part 1: General requirements for safety; 2. Collateral standard: electromagnetic compatibility; requirements and tests
EN ISO 60601-1-4	Medical electrical equipment – Part 1-4: General requirements for safety; Collateral standard: Programmable electrical medical systems
EN ISO 60601-2-22	Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment

The VICTUS Femtosecond Laser Platform has been found to perform equivalently to the predicate lasers for creation of a corneal flap in patients undergoing LASIK and for anterior capsulotomy during cataract surgery. Thus, the VICTUS Femtosecond Laser Platform and the predicate devices have similar safety, effectiveness, and performance profiles.

Non-clinical performance data

A variety of test procedures were conducted to demonstrate the performance of the proposed VICTUS Femtosecond Laser Platform in support of this premarket submission. The collected data were evaluated by comparing the mean values to the specified acceptance criteria and their 95% confidence intervals. Four different materials were used for the bench performance testing: porcine eyes, agarose gel, polyethylene terephthalate (PETG), and polymethyl methacrylate (PMMA). Scanning electronic microscopy has also been utilized to visually assess the results of the laser capsulotomy and flap procedures with the VICTUS Femtosecond Laser Platform. The resulting micrographs are compared qualitatively with images obtained from the predicate devices.

The testing showed that laser-assisted anterior capsulotomy performed with the VICTUS Femtosecond Laser Platform resulted in highly reproducible and accurate capsular tissue diameter, depth, height, and centration. Flaps created with the VICTUS Femtosecond Laser Platform were shown to result in highly accurate tissue diameter, thickness, and centration.

Clinical performance data

Clinical performance was evaluated in a clinical study using the VICTUS Femtosecond Laser Platform (VICTUS) for use in cataract procedures. This study included evaluation of femto-second laser anterior capsulotomy as compared to manual methods for cataract surgery. This was a randomized, controlled, open, prospective, single-center, multi-surgeon clinical study.

Enrolled subjects were randomly assigned to one of two groups: Group A had anterior capsulotomy as well as lens fragmentation performed by the VICTUS device prior to phacoemulsification (treatment), and Group B acted as a control group where the capsulotomy was performed manually prior to phacoemulsification.

119 eyes of the 118 subjects were included for analysis (one patient was treated bilaterally). The mean age of the study population was 60.0 ± 10.7 years (from 20 to 81 years). The VICTUS anterior capsulotomy procedure was shown to be comparable to the standard manual procedure capsulorhexis (CCC). The occurrence of adverse event or severe adverse event was not different between the two study groups up to 3-Month post-surgery. Treatment safety was good and slit lamp examinations at one day post-surgery as well as up to 3-Month post-surgery were consistent with those following the manual procedure. The observation rates of corneal edema, flare and trace anterior chamber cells post femto-surgery were comparable to those in the manual group. The centration of the IOL was good as determined by visual inspection during slit lamp examination at one day post-surgery as well as up to 3-Month post-surgery. The study population included cataract grades 1-5 as well as white/brown cataracts which did not pose any additional risks with the VICTUS laser-assisted anterior capsulotomy.

Additional parameters encompassed the completeness of the capsulotomy as well as the centration of the capsulotomy and implanted IOL as determined by visual inspection at the day of surgery. Overall, it can be concluded that the VICTUS can be used successfully for performance of anterior capsulotomy during cataract surgery.

Separately, flap thickness clinical data on 18 eyes was collected at a VICTUS site located outside of the USA. The data provided compared intended flap thickness (in microns) to the achieved flap thickness. The clinical data collected showed that the difference between the achieved mean and the intended mean (3.58µm) is within the acceptance criteria of 10µm, with a standard deviation of approximately 6µm.

The clinical data provided confirms that laser-assisted anterior capsulotomy is comparable to the standard manual procedure. The occurrence rates for adverse event, severe adverse event and treatment-related complications are comparable to manual capsulotomy.

Conclusion

The technological characteristics of the VICTUS Femtosecond Laser Platform are substantially equivalent to the technological characteristics of the previously cleared FEMTEC Laser Microkeratome (K033354) and the FEMTEC Laser System for Anterior Capsulotomy (K110427). The non-clinical and clinical data support that anterior capsulotomy and flap creation can be successfully executed by the VICTUS Femtosecond Laser Platform.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

JUL 31 2012

Technolas Perfect Vision GmbH
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San Francisco, CA 94114

Re: K120426
Trade/Device Name: VICTUS Femtosecond Laser Platform
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Femtosecond Laser
Regulatory Class: Class II
Product Code: OOE, HQF
Dated: July 13, 2012
Received: July 16, 2012

Dear Mr. Nehmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K120426

Device Name(s): VICTUS Femtosecond Laser Platform

Indications for Use:

The VICTUS Femtosecond Laser Platform is indicated for use for:

- the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.
- for anterior capsulotomy during cataract surgery.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120426